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February 23, 2021

VIA ECF
The Honorable Gregory H. Woods
Daniel Patrick Moynihan United States Courthouse
500 Pearl Street
New York, New York 10007-1312

Re: *Skiadas v. Acer Therapeutics Inc., et al., Case No. 1:19-cv-06137-GHW*

Dear Judge Woods:

We write on behalf of Lead Plaintiff Skiadas ("Plaintiff") in response to Defendants' February 18, 2021 pre-motion letter requesting leave to move to dismiss a portion of the Third Amended Class Action Complaint (the "TAC") (ECF. No. 104.) Plaintiff moved to file the TAC because the FDA documents that Defendants produced provided proof of significant additional wrongdoing by Defendants. They show that when Defendants explicitly asked the FDA if the Ong Trial was sufficient for approval of EDSIVO's NDA, the FDA did not agree and, instead, told Defendants that approval based on a single study was rare. The meeting minutes further showed that the FDA had warned Defendants for years that the Ong Trial had serious flaws: (1) it had a randomization imbalance between the celiprolol (the generic name for EDSIVO) and control groups, and (2) its results were not properly adjusted for the multiple interim analyses of efficacy conducted during the Trial and that the Trial was stopped early based on those improperly conducted interim analyses. Because of those flaws, the FDA concluded that the Ong Trial was not sufficient to show that EDSIVO was effective against vEDS and its results were not statistically significant. Based on this new information, the TAC (1) repleads Defendants' misstatements about the "guidance" that the FDA provided Defendants at the May 2017 meeting; (2) adds Defendants' misstatements that the Ong Trial had statistically significant results, showed efficacy, and that important phenotype characteristics were equally balanced between the celiprolol and control groups; and (3) pleads that the "FDA Agreed" statements that the Court previously sustained were false and misleading for the additional reason that Defendants failed to disclose that the FDA told Acer that approval based on a single trial was "rare" and that the FDA was concerned about flaws in the Ong Trial.[1] Defendants seek to dismiss only the first two categories of misstatements.[2]

Defendants' FDA Guidance Statements Were False and Misleading.

The FDA documents that Defendants produced show that Defendants' statements that the "FDA

[1] Defendants' Proposed TAC also included Defendants' statements that Acer's product candidates had a "de-risked profile," but, in an effort to streamline the TAC, Plaintiff elected not to include those statements in the final TAC.
[2] Defendants also claim that what they describe as their "status update[]" misstatements are not actionable. (TAC ¶¶ 152, 192.) Those statements also include misstatements about the Ong Trial's statistical significance and EDSIVO's efficacy, which render the statements misleading.

provided us with additional guidance on the expected presentation of the existing clinical data for EDSIVO™ to support the NDA filing" at a May 2017 meeting were misleading. (TAC ¶¶ 166, 179.) The minutes from that meeting show that the FDA did not simply give "guidance" on how to present the Ong Trial data. Instead, the FDA criticized the Ong Trial's randomization imbalance and interim analyses — concerns about how the *Trial was originally conducted that undermined the reliability of the results*. (*Id.* ¶ 76.) This information was highly material to investors since flaws in the original Ong Trial could not be easily remedied by Acer after the fact. Once Defendants made specific disclosures about the FDA's guidance concerning the Ong Trial data at the September 2017 meeting, they were required to disclose the FDA's negative comments about how the Trial was originally conducted since "once a company speaks on an issue or topic, there is a duty to tell the whole truth… The literal truth of an isolated statement is insufficient; the proper inquiry requires an examination of defendants' representations, taken together and in context." *Meyer v. Jinkosolar Holdings Co.*, 761 F.3d 245, 250-251 (2d Cir. 2014).

Defendants' argument that their omissions were not actionable because "[t]he FDA did not say Acer could not address the issues [with the Ong Trial]" is a red herring. Plaintiff's position is not that the FDA's criticism of the Ong Trial in September 2017 meeting made it 100% certain the FDA would reject EDSIVO. Instead, Plaintiff is arguing that Defendants' guidance statements were materially misleading because there was a much greater risk of rejection than Defendants' statements indicated since they failed to disclose that the FDA had serious concerns about the quality of the original Ong Trial data.. Accordingly, these statements are clearly actionable based on the new information in the minutes from the FDA's meetings with Acer.

Defendants' Statements Regarding the Ong Trial Were False and Misleading.

Defendants stated numerous times during the class period that the Ong Trial had statistically significant results and demonstrated the efficacy of celiprolol (TAC ¶¶ 152, 155, 157, 169 171, 172, 182, 183, 189, 190, 192) and that the important phenotype characteristics were equally balanced between celiprolol and control groups in the Trial (*id.* ¶¶ 156, 162, 170, 175, 186.) They made these statements while the FDA was warning them of exactly the opposite — that the Trial did not show efficacy, was not statistically significant, and the celiprolol and control groups had a randomization imbalance. While it is true that sponsors of a drug may not have the duty to disclose all negative FDA comments about a study,[3] they cannot make statements to investors that data is favorable without also disclosing the FDA's trepidations about the same data. *See Schueneman v. Arena Pharm., Inc.*, 840 F.3d 698, 709 (9th Cir. 2016) (holding that defendant's positive statements about animal studies were actionable because"[it] could have remained silent about the dispute or it could have addressed its discussions with the FDA head-on. But it could not represent that there was no controversy here because all the data was favorable"); *In re Amylin Pharm., Inc. Sec. Litig.*, No. 01CV1455 BTM (NLS), 2003 WL 21500525, at *8 (S.D. Cal. May 1, 2003) ("A company seeking FDA approval of a new drug clearly is not under any obligation to disclose every single issue raised by the FDA throughout the process. However, if the FDA expresses significant concerns regarding the sufficiency of the trials, the company cannot make affirmative

[3] None of Defendants' cases concern situations where the defendants were making positive statements about precisely the same thing that the FDA was warning them about. Notably, in *Tongue v. Sanofi*, 816 F.3d 199, 214 (2d Cir. 2016) and *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 524 (S.D.N.Y. 2015), the FDA approved the drug in question without any further clinical trials.

representations regarding the completeness or sufficiency of the trials without full disclosure.").

Defendants also cannot reasonably argue that their misstatements were not material because there was some public information about the flaws in Ong Trial. What is actionable is Acer's failure to disclose the FDA's serious concerns about the Ong Trial, not the flaws themselves. *See Schueneman.,* 840 F.3d at 709 ("It is the failure to disclose 'issues' and 'concerns' with the Rat Study and the FDA's interest in the outcome of those studies—not who was ultimately right about the underlying science—that matters."). Additionally, a "truth-on-the-market defense is intensely fact-specific and is rarely an appropriate basis for dismissing a § 10(b) complaint for failure to plead materiality." *Ganino v. Citizens Utilities Co*., 228 F.3d 154, 167 (2d Cir. 2000).

Plaintiff Pleads Scienter for the New Misstatements.

Scienter can be pled "by alleging facts (1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior." *In re Lehman Bros. Equity/Debt Securities Litig.*, 799 F. Supp. 2d 258, 293 (S.D.N.Y 2011). Recklessness meets the pleading requirement for scienter where defendants have "knowledge of facts or access to information contradicting their public statements." *Novak v. Kasaks*, 216 F.3d 300, 308 (2d Cir. 2000).

Defendants admit in their letter that Plaintiff pleads motive and opportunity for the same reason that the Court credited in its Order on Defendants' motion to dismiss the Second Amended Complaint ("SAC") — "[a]n executive at a company that will go belly up if it fails to fundraise…has a stronger incentive to bet the farm in a reckless gamble because the alternative is certain failure." *Skiadas v. Acer Therapeutics Inc.*, No. 1:19-CV-6137-GHW, 2020 WL 3268495, at *11 (S.D.N.Y. June 16, 2020). Additionally, that Defendants acted consciously or recklessly is pled even more strongly in the TAC than in was in the SAC. The SAC inferred that Defendants knowingly or recklessly made misrepresentations based on the FDA ultimate rejection of EDVISO. In contrast, because Plaintiff now has access to Acer's FDA meeting minutes, we now know that Defendant Schelling personally attended all the meetings, that the FDA put its serious concerns about the Ong Trial in writing, and that Defendant Palmin, as CFO, would have had access to those documents. *See Schueneman*, 840 F.3d at 709 (holding that failure to disclose FDA's concerns about animal study was sufficient to plead scienter); *Kalnit v. Eichler*, 264 F.3d 131, 142 (2d Cir. 2001) ("Securities fraud claims typically have sufficed to state a claim based on recklessness when they have specifically alleged defendants' knowledge of facts or access to information contradicting their public statements." (internal quotation marks omitted)).

Finally, Defendants make the same argument that the Court rejected in its Order on the motion to dismiss the SAC — that it would have been illogical for Acer to go forward with EDSIVO's NDA if it believed that the FDA's comments precluded approval. The Court rejected this argument because "allegations support the inference that Defendants rationally (though recklessly) gambled that the FDA would ultimately approve EDSIVO…without additional clinical development." *Skiadas*, 2020 WL 3268495 at *11. The same argument applies to the new allegations in the TAC.

Respectfully submitted,
/s/ *Laurence M. Rosen*

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